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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/682,459

10/08/2003

Richard S. Ginn

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12/04/2008

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EXAMINER

DORNBUSCH, DIANNE

ART UNIT

PAPER NUMBER

3773

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/682,459	<b>Applicant(s)</b> GINN ET AL.	
	<b>Examiner</b> DIANNE DORNBUSCH	<b>Art Unit</b> 3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 05 September 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 2-10 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2-10 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>09/05/2008, 10/23/2008</u> .                                  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 7 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 7 claims a skin outer surface that facilitates advancement of the elongated member into the opening through tissue. This claim is indefinite, since in claim 2, the skin is claimed as being between the outer surface of the elongated member and the closure element, therefore it is not possible for the elongated member to slide on the outer surface of the skin when the skin is placed on the outer surface of the elongated member.

### ***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 2, 3, 5, 8, 9, and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Janzen (5,437,631) in view of Mikus et al. (6,517,569).

Claim 2:

Janzen discloses a method for delivering a closure element (48) to seal an opening through tissue, the closure element (48) being carried on a proximal end of an elongate member (32) such that a proximal end of the closure element (48) is spaced apart from an outer surface of the elongate member (the closure element is slid onto the elongated member starting at the proximal end where a portion will be spaced apart from the outer surface of the elongated member), the method comprising: inserting the distal end of the elongate member (32) into an opening through tissue (Fig. 2); inserting a distal end of an actuator member (45, 43a) between the proximal end of the closure element (48) and the outer surface of the elongate member (32) until the distal end of the actuator member is coupled with the closure element (Fig. 4-5 and Col. 5 Lines40-42); advancing the actuator member (45) distally, thereby advancing the closure element (48) towards the distal end of the elongate member (32) (Fig. 5-6); engaging tissue adjacent the distal end of the elongate member (32) with tissue engaging elements (the closure element is a sealant which contains hemostatic material in the form of fibrous collagen (used as a sealant) that activates the clotting action in order to close the tissue, hence the engaging elements are the parts of the material which interact with the blood to cause the clotting action) on the closure element (48); and withdrawing the elongate member (32) from the opening, thereby leaving the closure element (48) to close the opening (Col. 5 Lines44-53). Furthermore, Janzen discloses a skin, or sleeve member, (43b) overlying at least a portion of the outer surface between the closure element and a distal end of the elongate member and at least partially overlying the closure element (Fig. 4-6 where as the actuator moves distally, the skin

will be surrounding the distal outer surface of the elongated member and it overlies the closure element as seen in the figures).

Janzen discloses the claimed invention except for the skin separating from the outer surface of the elongate member as the closure element is advanced towards the distal end.

Mikus teaches a skin or sleeve 20 overlying at least a portion of an outer surface between a closure element (30, 50) and a distal end of an elongate member (15) and wherein the skin separates or split from the outer surface of the elongate member from a proximal end of the skin toward a distal end of the skin when the closure element is advanced (Figures 1,3-4 and Col. 3, Lines13-29 and Col. 5, Lines28-40).

It would have been obvious to one of ordinary skill in the art at the time of invention to modify Janzen with a splittable skin, as taught by Mikus, since it was known in the art that skins or sleeves are commonly used in deployment devices to conveniently protect delivery devices and are often subsequently opened or removed in order to unveil the delivery device without additional manipulation by a secondary instrument.

Claims 3 and 5:

Janzen discloses the claimed invention, except for the skin comprising a weakened region extending towards the distal end of the elongate member, the weakened region tearing as the closure element is advanced towards the distal end of the elongate member, and the skin expanding to a cross-section that is larger than

Art Unit: 3773

cross-section of the elongate member as the elongated member is advanced towards the distal end.

Mikus teaches the skin (20) comprising a weakened region (22) extending towards the distal end of the elongate member, the weakened region tearing as the closure element is advanced towards the distal end of the elongate member, and the skin expanding to a cross-section that is larger than a cross-section of the elongate member as the closure element is advanced towards the distal end (Figures 1 and 3-4).

It would have been obvious to one of ordinary skill in the art to provide a skin with a weakened region, as taught by Mikus, to Janzen since it was known in the art that skins or sheaths are commonly used in deployment devices to protect delivery devices with weakened regions to serve as a simple opening mechanism that does not require a second instrument.

Claim 8: Janzen discloses that the opening through tissue extends through one or more layers of fascia (16, 18, 12, 20), and wherein the skin facilitates advancement of the carrier assembly through the one or more layers of fascia (Fig. 1-6).

Claim 9: Janzen discloses that the opening through tissue communicates with a blood vessel (20), and wherein leaving the closure element to close the opening comprises leaving the closure element to substantially seal the opening from blood flow therethrough with the closure element (Fig. 6 and Col. 5 Lines 40-55).

Claim 10: Janzen discloses that the elongate member (32) comprises a lumen extending between the proximal and distal ends (Fig. 3-5), and wherein the method

further comprises inserting one or more instruments through the lumen into the blood vessel (Fig. 2 and Col. 5 Lines26-30).

5. Claims 4 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Janzen (5,437,631) in view of Mikus et al. (6,517,569) and further in view of Martinez (5,593,412).

Claim 4:

Janzen in view of Mikus disclose the claimed invention, except for the skin comprising a flap extending generally axially along the outer surface of the elongate member and overlying an adjacent region of the skin, and wherein the flap is released from the adjacent region as the carrier assembly is advanced towards the distal end of the elongate member, thereby allowing the skin to separate from the outer surface.

Martinez teaches the skin (18) comprising a flap (fingers 51-55) extending generally axially along the outer surface of the elongate member (12) and overlying an adjacent region of the skin (Fig. 1-3 where the flaps are adjacent to the weekend areas (41-45) which attaches all he fingers together as best seen in Fig. 2A) fingers as seen in the figures), and wherein the flap is released from the adjacent region (Fig. 2B-5) as the carrier assembly (14) is advanced towards the distal end of the elongate member, thereby allowing the skin to separate from the outer surface (Fig. 2-5).

It would have been obvious to one of ordinary skill to provide a skin with flaps, as taught by Martinez, to Janzen in view of Mikus in order to have a closed tapered area which would facilitate insertion through the tissue prior to separating the skin.

Claim 7:

Janzen in view of Mikus disclose the claimed invention, except for the skin comprising an outer surface that is substantially slippery for facilitating advancement of the elongate member into the opening through tissue.

Martinez teaches the skin comprising an outer surface that is substantially slippery for facilitating advancement of the elongate member into the opening through tissue and that it allows for retraction of the sheath and allows for expansion for the element onto which it is disposed (Col. 3, Lines 30-42 and Col. 4, Lines 53-67 and Col. 5 Lines1-2).

It would have been obvious to one of ordinary skill to provide a skin with a slippery outer surface, as taught by Martinez, to Janzen in view of Mikus since it was known in the art that a lubricated, slippery surfaces allow for facilitated translational movement and also in order to allow for expansion of the elongate member or the element onto which it is disposed.

6. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Janzen (5,437,631) in view of Mikus et al. (6,517,569) and further in view of Kanner et al. (5,868,755).

Janzen in view of Mikus disclose the claimed invention except for the skin being bonded to the outer surface of the elongate member by an adhesive and wherein the adhesive has sufficient adhesive strength such that the skin is peeled away from the outer surface as the carrier assembly is advanced towards the distal end.

Kanner teaches a skin (1) being bonded to the outer surface of the elongate member by an adhesive and wherein the adhesive has sufficient adhesive strength such that the skin is peeled away from the outer surface as the carrier assembly is advanced towards the distal end (Col. 4, Lines 1-16).

It would have been obvious to one of ordinary skill in the art to provide a skin bonded to the outer surface to the elongate member, as taught by Kanner, to Janzen in view of Mikus, since it was known in the art to provide adhesives that provide temporary security.

### ***Response to Arguments***

7. Regarding claims 2-8 which were indicated as being allowable on the office action mailed on April 2, 2008; regrettably the allowance has been withdrawn by the examiner due to a newly found prior art reference.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DIANNE DORNBUSCH whose telephone number is (571)270-3515. The examiner can normally be reached on Monday through Thursday 7:30 am to 5:00 pm Eastern.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3773

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/D. D./

Examiner, Art Unit 3773

/(Jackie) Tan-Uyen T. Ho/

Supervisory Patent Examiner, Art Unit 3773